

***Remarks***

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 36, 37, 40, 41, 43, 44, 46-49, 58 and 59 are pending in the application, with claim 36 being the independent claim. Claims 1-35, 38, 39, 42, 45 and 50-57 were cancelled without prejudice to or disclaimer of the subject matter therein. New claims 58 and 59 are sought to be added. These changes are believed to introduce no new matter, and their entry is respectfully requested.

This Supplemental Amendment is being filed in response to the Examiner's comments in the Office Action mailed December 2, 2003. As indicated on the RCE Transmittal form, the Examiner is respectfully requested to enter the Amendments to the Claims accompanied by the Amendment and Reply Under 37 C.F.R. § 1.116 submitted October 7, 2003, and to reconsider the arguments set forth therein. Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

***Rejections under 35 U.S.C. § 112, First Paragraph***

In the Office Action mailed December 2, 2003, the Examiner asserts that claims 36, 37, 40, 41, 43, 44 and 46-49 would be rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Examiner asserts that the specification does not provide a written description of the entire genus of SCC1 fragments and variants thereof which can be used to assay for separin function/activity relationship.

However, Applicants respectfully note that the specification does provide support for additional "fragments" or "variants" of SCC1 that can be cleaved by separin or have a separin cleavage site. For example, Fig. 14 shows cleavage products from truncated SCC1 proteins, e.g., SCC1 proteins having amino acids deleted from the N-terminal end, wherein translation of SCC1 was started at, e.g., amino acid residues 145, 155, 165, and 171, and SCC1 proteins having amino acids deleted from the C-terminal end, wherein translation was terminated at, e.g., amino acid residues 169, 173, and 183. (See also specification, at p. 15, l. 3 *et seq.*)

In addition, given the disclosure of the ExxR motif in SEQ ID NO:1 (see specification, at p. 15, l. 3 *et seq.*) and the truncated proteins provided in the specification, all possible fragments and variants could be envisioned by one of skill in the art as of the priority date of the captioned application. Applicants assert that additional disclosure is not needed in order for the claimed invention to be adequately described.

The test for the written description requirement is whether one skilled in the art could reasonably conclude that the inventor has possession of the claimed invention in the specification as filed. *See Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). The Federal Circuit recently re-emphasized the well-settled principle of law that "[t]he written description requirement does not require

the applicant 'to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [they] invented what is claimed.'" *Union Oil of Cal. v. Atlantic Richfield Co.*, 208 F.3d 989, 997 (Fed. Cir. 2000) (quoting *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989)). Furthermore, an applicant is not required to explicitly describe the subject matter. *See Unocal*, 208 F.3d at 1000; *see also* M.P.E.P. § 2163.02 ("The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement."). The court emphasized the importance of what the person of ordinary skill in the art would understand from reading the specification, rather than whether the specific embodiments had been explicitly described or exemplified. Indeed, as the court noted, "the issue is whether one of skill in the art could *derive* the claimed ranges from the patent's disclosure." *Unocal*, 208 F.3d at 1001 (emphasis added).

In view of the above, Applicants submit that a person of ordinary skill in the art would understand from reading the specification that Applicants had possession of the claimed subject matter. Those skilled in the art are well aware of procedures for generating fragments and the description need only describe in detail that which is new or not conventional. *See Hybritech v. Monoclonal Antibodies*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

In addition, Applicants have disclosed relevant identifying characteristics of the members of the claimed genus: the fragment must be cleavable by separin or have a separin cleavage site. Applicants submit that the disclosure of such identifying characteristics distinguish the claimed invention from other materials and would lead one

skilled in the art to conclude that Applicants were in possession of the claimed invention. *See University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Accordingly, Applicants respectfully request that the rejection be withdrawn.

### ***Conclusion***

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Judith U. Kim  
Attorney for Applicants  
Registration No. 40,679

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1100 New York Avenue, N.W.  
Washington, D.C. 20005-3934  
(202) 371-2600